patient care services affected due to the strike by the doctors, nurses and other staffs are closely monitored. Contingency plans are available in each of the Central Government Hospitals to avoid disruption of the patient care services.

**Clinical trial on new malaria drug**

92. SHRIMATI JAYA BACHCHAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government had decided to junk the anti-malarial drug chloroquine in favour of a new drug combination;

(b) if so, what are the details in this regard;

(c) whether any clinical trials of the new combination of drugs have been carried out; and

(d) if so, the results thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) No, Sir. Chloroquine is being used for the treatment of *P. vivax* in entire country and *P. falciparum* cases in areas where Pf. parasite is sensitive to chloroquine.

ACT (Artesunate plus Sulfadoxine Pyrimethamine) combination is being used for the treatment of confirmed *P. falciparum* cases in chloroquine resistant areas and identified high Pf. predominant districts of the country.

(c) and (d) Various clinical trials on ACT combination have been carried out by research institutions like NIMR.

All the combinations have shown excellent efficacy (cure rate >95%) and are well tolerated. Details about the drugs that have been evaluated are enclosed as statement.

***Statement***

*Clinical trials conducted by with Artesunate combination therapy at National Institute Malaria Research.*

| Sl.No. | ACT | Phase of Trial | Collaboration | Study Site |
|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 |
| 1. | Artemether-Lumefantrine | Surveillance | USAID | Assam and Orissa |
| 2. | Artekin (Dilhydroartemisinin+ Priperaquine Phosphate) (Fixed Dose) | III | MMV | Guwahati, Mangalore, Goa |
| 3. | AS+AQ (Artesunate + Amodiaquine) (Fixed Dose) | III | DNDi | Ranchi, Rourkela |

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| 4. | Arterolane Maleate + Priperaquine Phosphate (Fixed Dose) | II | Ranbaxy | Bangkok, Rourkela, Jamshedpur |
| 5. | AS+MQ (Artesunate +Mefloquine) (Fixed Dose) | III | DNDi | Goa, Mangalore |
| 6. | Pyramax for *P. vivax* (Fixed Dose) | III | MMV, Shinphong | Mangalore |
| 7. | Pyramax for *P. falciparum* | III | MMV, Shinphong | Mangalore |

**Infant deaths due to clinical trials**

93. SHRI N.R. GOVINDARAJAR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that forty-nine infants died at AIIMS while being subjected to clinical trials for testing new drugs and therapies over the last two and a half years;

(b) if so, the details thereof;

(c) whether foreign manufactured medicines were listed during the trials;

(d) if so, the details thereof;

(e) how many children were admitted for these clinical trials and how many sets of trials were conducted on these children;

(f) whether the parents of these children were well informed about these clinical trials and were given social counseling before these trials; and

(g) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Death of 49 children enrolled in 6 clinical trials at All India Institute of Medical Sciences, New Delhi was reported between January 2006 and June, 2008. These consisted of 4 clinical trials with drugs as interventions, one trial with feeding protocol and one with Continuous Positive Airway Pressure (CPAP). It was observed that 4142 children were enrolled in 42 clinical trials in the Department of Paediatrics.

(c) and (d) Yes, Sir. In one case, the foreign manufactured medicines were used during the trials. Zinc deficiency is of public health importance in India because of the problem of widespread zinc deficiency. WHO/UNICEF, Indian Academy of Pediatrics and the National Rural Health Mission, Govt. of India recommend use of zinc in treatment of acute diarrhea in all infants and children. This policy is based on large well done randomized controlled studies from many